

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

BIOGEN INTERNATIONAL GMBH and
BIOGEN MA INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:17-cv-116-IMK

DEFENDANT'S EXPERT WITNESS BIOGRAPHICAL SKETCHES

A. BENJAMIN M. GREENBERG, M.D.

Dr. Benjamin Greenberg received a Bachelor of Arts in History of Medicine and a Master of Health Science in Molecular Microbiology and Immunology from Johns Hopkins School of Public Health in 1997. He received his M.D. from Baylor College of Medicine in 2001. Dr. Greenberg completed his residency in Neurology in 2005 and was a postdoctoral fellow in Microbiology and Immunology from 2005 to 2007 at Johns Hopkins School of Public Health. From 2005 to 2008 he also held academic appointments and was a practicing neurologist while at Johns Hopkins. Dr. Greenberg is currently a Professor in the Department of Neurology and the Department of Pediatrics at the University of Texas Southwestern, as well as a practicing neurologist at hospitals associated with the University of Texas Southwestern. He serves as the Director of three different programs at the University of Texas Southwestern, including the Multiple Sclerosis Program, the Transverse Myelitis and Neuromyelitis Optica Program, and the Pediatric CONQUER Program.

Dr. Greenberg is currently involved with clinical and translational research projects, including overseeing a translational research program that identifies novel biomarkers of disease in patients with multiple sclerosis. His research has resulted in over 110 publications and presentations on more than 50 occasions at national and international scientific meetings. Dr. Greenberg has served as the principal investigator on numerous interventional and observational multiple sclerosis clinical trials and coordinated the activities of phase 1, phase 2, phase 3, and phase 4 clinical trials. He has been a reviewer for multiple journals, including European Neurology, Neurology, Annals of Neurology, Journal of Neurology, Journal of Immunology, and Multiple Sclerosis Journal.

Dr. Greenberg is expected to testify regarding the invalidity of the asserted claims of United States Patent No. 8,399,514 (“the ’514 patent”), on issues including invalidity of the claims due to obviousness, the lack of any secondary considerations of nonobviousness including, for example, unexpected results or satisfaction of any long-felt but unmet need, the lack of written description, and the failure to enable the claims.

B. NEAL M. DAVIES, BSc(PHARM), PH.D., R.Ph.

Dr. Neal Davies received an undergraduate degree in Pharmacy from the University of Alberta in 1991 and completed a Ph.D. in pharmaceutical sciences, specializing in pharmacokinetics, at the University of Alberta in 1996. His post-doctoral training was in pharmacology and toxicology at the University of Calgary. Dr. Davies has held academic positions at the University of Sydney in the Faculty of Pharmacy and at Washington State University in the College of Pharmacy, and he was previously Dean of the Faculty of Pharmacy at the University of Manitoba. Dr. Davies is currently Dean and Professor in the Faculty of Pharmacy and Pharmaceutical Sciences at the University of Alberta. He maintains an active research

program focused on pharmacokinetics and drug delivery as well as basic and clinical pharmaceutical sciences. Dr. Davies's academic work has been cited over 10,000 times and has been disseminated broadly through numerous journal publications, three books and book chapters, abstracts, and invited conference presentations. Dr. Davies also serves as a reviewer and is on the editorial board of several pharmaceutical and pharmacological science journals.

Dr. Davies is expected to testify regarding the invalidity of the asserted claims of the '514 patent, on issues including the lack of any secondary considerations of nonobviousness such as, for example, unexpected success.

C. ROBERT MAKUCH, PH.D.

Dr. Robert Makuch received a Bachelor of Arts in Mathematics from the University of Connecticut in 1972 and a Master's Degree in Mathematics from the University of Washington in 1974. He obtained his Master of Philosophy in Biostatistics from Yale University in 1976, and Doctor of Philosophy in Biostatistics from Yale University in 1977. Dr. Makuch has been a tenured Full Professor in the Department of Biostatistics at Yale University's School of Medicine since 1990. He is also the creator and current Director of the Regulatory Affairs Program and Chairman of the Regulatory Affairs Advisory Board at Yale University. From 2002 to 2007, he was appointed to serve as a Special Government Employee to the Food and Drug Administration to support its analysis and interpretation of clinical trials and epidemiologic studies. Dr. Makuch has also advised foreign government regulators on their own regulatory frameworks, including over 11 years of intensive training for senior delegations of the Chinese Food and Drug Administration. In addition, he has advised many pharmaceutical companies and has served on their global regulatory drug advisory boards and drug development committees. Dr. Makuch's research has focused primarily on the design, conduct, analysis, and interpretation of clinical and

preclinical data obtained from preclinical experiments, clinical trials, and epidemiologic studies. He is an author or co-author on over 200 peer-reviewed publications, and has given numerous presentations on these topics at national and international meetings, universities, and government agencies.

Dr. Makuch's anticipated testimony will concern the invalidity of the asserted claims of the '514 patent, including the lack of any secondary considerations of nonobviousness such as, for example, unexpected success.

D. MR. IVAN HOFMANN

Mr. Ivan Hofmann graduated from the University of Notre Dame *magna cum laude* in 1994 with a Bachelor of Business Administration, double majoring in Economics and Accounting. He is currently the Vice President and Managing Director at Gleason IP, which is an economic, accounting, and financial consulting firm. Mr. Hofmann is a Certified Public Accountant and a Certified Licensing Professional, a designation granted by the Licensing Executives Society to professionals with demonstrated knowledge and experience in the areas of intellectual property and licensing. He has extensive work experience in the pharmaceutical and life sciences industry, having performed financial and economic analysis for hundreds of prescription pharmaceutical and biologic products, covering virtually every major therapeutic class of drugs. Mr. Hofmann has served as an expert in numerous matters involving the pharmaceutical and life sciences industry that have involved the role of brand versus generic competition. He has been designated as a testifying expert in federal and state courts, the United States International Trade Commission, the Patent Trial and Appeal Board, and on matters before various domestic and international arbitration panels. Mr. Hofmann has also been engaged by the United States Patent and Trademark

Office and the Office of the Solicitor as an expert to analyze and testify on economic issues involving intellectual property.

Mr. Hofmann's anticipated testimony will concern the invalidity of the asserted claims of the '514 patent, including the lack of any secondary considerations of nonobviousness such as, for example, commercial success.

Dated: January 16, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on January 16, 2020, I filed the foregoing DEFENDANT'S EXPERT WITNESSES BIOGRAPHICAL SKETCHES with the CM/ECF system, which will cause notice of the filing to be served on the following counsel of record:

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